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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,232	07/22/2003	Nagy Adly Habib	380048-97	8627

7590 06/12/2007
Attn: Barbara A. Wrigley
OPPENHEIMER WOLFF & DONNELLY LLP
45 South Seventh Street
Suite 3300
Minneapolis, MN 55402

EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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06/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/625,232	Applicant(s) HABIB ET AL.	
	Examiner Aaron Roane	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 12-19 and 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in still further view of Swanson (USPN 6,267,760).

Regarding claims 1, 3, 5, 6, 12-14, 19 Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of

tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. (Edwards I) fail to disclose to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Edwards (Edwards II) discloses a tissue heating device having retractable needles (12) and teaches the alternative/equivalent energy delivery of microwave with cooling means and RF, see col. 1-7 and particularly col. 7, lines 28-38 and figures 1-6. Finally, Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al. (Edwards I), as is well known in

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the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, as further taught by Edwards (Edwards II), to use microwave energy as an alternate means of heating tissue, and as finally taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue.

Regarding claims 2 and 4, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson disclose the claimed invention, see Edwards II col. 6-9.

Regarding claims 15-18, 28-31 and 33-36, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson disclose the claimed invention, see Edwards et al. col. 6-14 and figure 16.

Regarding claims 25-27, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson disclose the claimed invention, see Edwards et al. figures 1-16.

Regarding claim 32, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson disclose the claimed invention, see the conducting wires connected to the needles of (Edwards I) in figures 1-16.

Claims 7-11 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in further view of Swanson

(USPN 6,267,760) as applied to claims 1, 3 and 6 above, and further in view of admitted prior art.

Regarding claims 7-11 and 20-24 Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson disclose the claimed invention in further view of Applicant's admission on the record that the claimed species are no patentably distinct as noted above.

Response to Arguments

Applicant's arguments filed 4/5/2007 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

On the last two lines of page 2 of 13 through the first full paragraph of page 3 of 13, Applicant asserts the examiner "has not established a prima facie case of obviousness." Applicant goes on to outline the basis for a finding of obviousness. The examiner disagrees as to the completeness presented by Applicant. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common

sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In *re* Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Next, on page 4 of 13, the first full paragraph through the last line on page 5 of 13, Applicant refutes the use of Edwards I and Swanson individually and argues against the rejection based on Edwards I and Swanson individually and not what they collectively teach one of ordinary skill in the art. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Next, on page 6 of 13, lines 1-10, Applicant asserts "Swanson does not teach advancing its probe to a desired depth in order to make an incision as claimed by Applicant in claim 3." Swanson discloses making an incision in the treated tissue and further applying energy again to further coagulate/treat tissue to a desirable depth so no bleeding occurs, see above rejection and cited passages therein.

Next Applicant refutes Swanson and Edwards I again in an individual manner ignoring what the combined teachings of the references would have suggested to those of ordinary skill in the art. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane
June 5, 2007

A.R.


ROY D. GIBSON
PRIMARY EXAMINER